REMARKS

In the April 6, 2006 Office Action, the Examiner imposed a restriction under 35 U.S.C. §121 to one of the following Groups:

I. Claims 29-35, drawn to a method for the treatment of Syndrome X comprising the oral administration to a human subject of an effective amount of a xenobiotic fatty acid compound;

II. Claims 36-41, drawn to a method for the treatment of dyslipoproteinemia comprising the oral administration to a human subject of an effective amount of a xenobiotic fatty acid compound;

III. Claims 42-48, drawn to a method for lowering plasma levels of triglycerides in a human subject comprising the oral administration to the subject of an effective amount of xenobiotic fatty acid compound; and

IV. Claims 49-54, drawn to a method for increasing plasma levels of HDL cholesterol comprising the oral administration to a human subject of an effective amount of a xenobiotic fatty acid compound.

In addition, as indicated on page 4 of the March 6, 2006 Office Action, a species election is required with respect to the R moiety of the xenobiotic fatty acid compounds defined by the formula R-COOH.

The Examiner stated that claims 29-54 are generic.

For the reasons set forth in the March 6, 2006 Office Action, the Examiner alleged that these inventions are distinct and that restriction for examination purposes as indicated is proper.

In the March 6, 2006 Office Action, the Examiner alleged that Inventions I through IV are patentably distinct. The Examiner stated that the inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints. The Examiner stated that in the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention I (i.e., treating Syndrome X in a subject) is distinct from the therapeutic objective of, for example, Invention II (i.e., treating dyslipoproteinemia in a subject), of which each is distinct from the therapeutic objectives of any one or more of Inventions III or IV.

The Examiner stated that Inventions I through IV are held to be patentably distinct because the treatment of any one of Inventions I through IV would not necessarily result in the treatment of the other invention. The Examiner stated that the patient populations in which each method would be practiced are distinctly different (e.g., patients requiring the treatment of Syndrome X versus patients requiring the treatment of dyslipoproteinemia), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. The Examiner conceded that there is

overlap in the groups of patients experiencing, for example, Syndrome X, and those experiencing, for example, dyslipoproteinemia. The Examiner stated that the therapeutic objectives, endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

The Examiner stated that furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, Syndrome X, would necessarily be independent and distinct from that required for the treatment of patients with, for example, dyslipoproteinemia, due to the differences in etiology of such a condition and the activity of the claimed agents in treating such a condition. The Examiner stated that moreover, one skilled in the art could practice the invention of any one or more of Inventions I, II, III or IV without practicing the invention of any one of the other inventions. The Examiner stated that Inventions I through IV are properly considered patentably distinct from one another.

The Examiner stated that because these inventions are distinct for the reasons given above and the search required for any one of Groups I through IV is not required for any one of the other groups, the inventions are held to be distinct and restriction for examination purposes as indicated is proper.

The Examiner stated that this application contains claims directed to the following patentably distinct species of xenobiotic fatty acid compounds defined by the formula R-COOH, wherein R may be any of the moieties recited in present claim

29, for example.

The Examiner stated that the species are independent or distinct because the species of xenobiotic fatty acid compounds recited in the present claims are each structurally, functionally and/or chemically distinct from any one other xenobiotic fatty acid compound recited in the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other xenobiotic fatty acid compounds recited in the claims. The Examiner stated that notwithstanding that applicant may have established an underlying common function to a combination of this broad genus of compounds, namely, that they are capable of treating Syndrome X, dyslipoproteinemia, lowering plasma triglycerides or increasing plasma HDL cholesterol in a human subject, it remains that the art does not necessarily recognize such a shared function as being common to each of the huge number of compounds encompassed by the claims. The Examiner stated that despite the fact that there may be incidental overlap between any one or more of the compounds contained within the claims, such does not change the fact that each of the xenobiotic fatty acid compounds encompassed by the claims are distinct from one another because they lack a common physical structure or function and, therefore, are considered patentably distinct. The Examiner stated that in addition, the discovery of any one of the presently claimed compounds would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other compounds of the present claims.

In response, applicant elects Group I, i.e. claims 29-35, drawn to a method for the treatment of Syndrome X comprising the oral administration to a human subject of an effective amount of a xenobiotic fatty acid compound, with traverse, for initial examination.

In addition, applicant elects the species of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid which is specifically recited in claims 32 and 33, and covered by claims 29-31.

Applicant, however, respectfully requests that the Examiner reconsider and withdraw the restriction requirement for the reasons that follow.

The Restriction Requirement Is Improper In Its Entirety

The Examiner stated that Inventions I-IV are held to be patentably distinct because the treatment of any one of Inventions I through IV would not necessarily result in the treatment of the other invention.

Applicant respectfully disagrees with the Examiner's assertion of restrictable subject matter set forth in the April 6, 2006 Office Action. Under 35 U.S.C. §121, restriction may be required if two or more "independent and distinct" inventions are claimed in one application.

Applicant maintains that the inventions of Groups I-IV are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. As disclosed in the instant specification, this invention relates to novel methods of treating Syndrome X,

which comprises some or all of dislipoproteinemia (which itself manifests hypercholesterolemia-hypertriglyceridemia, and low HDL-cholesterol), obesity, impaired glucose tolerance, essential hypertension and thrombogenic/fibrinolytic defects (see, for example, page 10, last full paragraph, of the subject specification). Therefore, successful treatment of any of these conditions would result in improvement of Syndrome X. Accordingly, applicants maintain that Groups I-IV are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction were not required.

Applicant respectfully submits that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to Groups II-IV, i.e. directed to methods for treating dyslipoproteinemia, lowering plasma levels of triglycerides and increasing plasma levels of HDL cholesterol, would not pose a serious burden once the prior art for the claims of Groups I, i.e. directed to a method of treating Syndrome X, has been identified, as discussed above. In addition, and as the Examiner conceded on page 2 of the March 6, 2006 Office Action, the subject matter of Groups I-IV share the same classification.

Therefore, there is no undue burden on the Examiner to examine Groups I-IV together in the subject application. Hence, applicant maintains that the Examiner must examine the claims of Groups I-IV, i.e. claims 29-54, on the merits.

In view of the foregoing, applicant maintains that restriction is not proper under 35 U.S.C. §121, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White
Registration No. 28,678
Attorney for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
(212) 278-0400

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John P. White 4/6/06

John P. White Date
Reg. No. 28,678